JUN 2 - 2005

K043340

510(k) Summary

for

***EZ Smart* Blood Glucose Monitoring System**
New 510(k) For Additional Labeling And Indication For Alternative Site Testing

1. **DATE PREPARED**

December 3, 2004

2. **SPONSOR INFORMATION**

Address

VIP Diagnostics LLC
1796 Clove Road
Staten Island, NY 10304

Contact Person: George P. Drogaris, MS R.Ph.

(800) 566-3480 (telephone)
(718) 390-0473 (facsimile)

Outside Regulatory Counsel

Foley & Lardner LLP
3000 K St., NW
Suite 500
Washington, DC 20007

Contact Person: David L. Rosen, B.S.Pharm., J.D.

(202) 672-5430 (telephone)
(202) 672-5399 (facsimile)

3. **DEVICE NAME**

Proprietary Name:	*EZ Smart* Blood Glucose Monitoring System
Common/Usual Name:	Blood Glucose Monitoring System
Classification Name:	Glucose Test System (per 21 C.F.R § 862.1345 (2003))

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4. DEVICE DESCRIPTION AND INTENDED USE

The *EZ Smart* Blood Glucose Test Strips are used with the *EZ Smart* Meter to measure Glucose (sugar) in whole blood. The *EZ Smart* Test strips are for testing outside the body (in vitro diagnostic use). The *EZ Smart* Blood Glucose Monitoring System is intended for use in the home and in the professional settings to monitor blood glucose levels for better glucose level control among diabetics.

The *EZ Smart* Blood Glucose Monitoring System is indicated for use with capillary whole blood samples drawn from the fingertip and forearm.

5. PREDICATE DEVICE

1. Predicate device name

   EZ Smart Blood Glucose Monitoring System
   Bayer Elite XL with the Elite Test Strips
   Bayer Elite with the Elite Test Strips

2. Predicate K Number

   K040848 (EZ Smart)
   K984006 (Bayer Elite XL)
   K964630 (Bayer Elite)
   K991242 (Bayer Elite Test Strips)

3. Substantial Equivalence Comparison

The modifications to the device encompass labeling changes only. There has been no changed to the intended use, fundamental scientific technology, physical design, operating principles, functionality or material composition of the device systems.

Modified labeling additions to *EZ Smart*:

Note: Alternative Site Testing
Consult with your healthcare professional prior to testing from a site other than your fingertips.

Under certain conditions, blood glucose testing results from sites other than your fingertip may be significantly different. These differences may vary from

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individual to individual, and are physiological differences caused by factors such as food intake, health state and medication being used.

The conditions in which these differences are more likely to occur are when your blood glucose is changing rapidly such as following a meal, an insulin dose, or associated with physical exercise. When blood glucose is changing rapidly, fingertip samples show these changes more quickly than other sample sites.

Use alternative test sites only for testing prior to, or more than two hours after meals, insulin dose, or physical exercise.

You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin relations) such as when driving a car, particularly if you suffer from hypoglycemia unawareness, as alternative site testing may fail to detect hypoglycemia.

If you perform testing other than from a fingertip (such as the forearm):

A. Select a soft, fleshy area of skin that is free from hair and visible veins.

B. Wash the puncture site with soap and warm water. Rinse and dry thoroughly. This ensures cleanliness and increases blood flow to the puncture site.

C. After you have determined the proper depth of your selected site, set the lancing device for that depth of puncture. Firmly press the lancing device against the skin at the selected lancing site, then press the button to lance the skin. When a drop of blood forms on the surface of your skin, bring the meter and test strip up to touch the drop.

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6. PERFORMANCE CHARACTERISTIC SUMMARY

There has been no change to the performance characteristics of the device system.

7. TECHNOLOGICAL CHARACTERISTICS

There has been no changes to the fundamental scientific technology.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 - 2005

VIP International Wholesales, Corp.
c/o David L. Rosen, B.S. Pharm., J.D.
Foley & Lardner LLP
3000 K Street, NW, Suite 500
Washington, DC 20007-5143

Re: k043340
Trade/Device Name: EZ Smart Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: April 11, 2005
Received: April 11, 2005

Dear Mr. Rosen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K 043340

Device Name: EZ Smart Blood Glucose Monitoring System

Indications For Use: The EZ Smart Blood Glucose Test Strips are used with the EZ Smart Meter to measure Glucose (sugar) in the whole blood. The EZ Smart Test strips are for testing outside the body (in vitro diagnostic use). The EZ Smart Blood Glucose Monitoring System is intended for use in the home and in the professional settings to monitor blood glucose levels for better glucose level control among diabetics.

The EZ Smart Blood Glucose Monitoring System is indicated for use with capillary whole blood samples drawn from the fingertips and forearm.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ruth A Chesler

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K043340